## Azinphos-Methyl Technical Briefing Slide Presentation

May 19, 1999

US EPA Office of Pesticide Programs

#### **Concordance of Slides with Assessments**

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14 - 17	Use Profile	Quantitative Usage Assessment
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#### Azinphos-Methyl Technical Briefing



May 19, 1999

# Introduction and Background Information

#### Azinphos-Methyl Purpose of the Briefing

- **★** Purpose of the Briefing
- **★** Public Participation
- **★** Regulatory History
- **★** Use Profile

#### Introduction

#### **Purpose of Briefing**

- Review risk assessment for azinphosmethyl
- Begin public participation period on risk mitigation strategies

#### **Azinphos-Methyl Risk Assessments Consider:**

- Dietary risk:
  - food, drinking water, and aggregate
- Worker risk:
  - applicators, handlers, and harvesters (reentry)
- Ecological risks:
  - birds, mammals, fish, and other aquatic species

#### Not Included in Azinphos-Methyl Assessment:

- Azinphos-methyl has no residential or public health uses:
  - currently developing method to address secondary exposure

## TRAC Pilot Public Participation Process for Azinphos-Methyl

Phase	Health Effects Assessment	Ecological Assessment
1 "Error Only" Review	7/98	11/98
2 Public Docket Opened	8/98	1/99
3 Comment Period Completed	10/98	3/99
4 Revised Assessment Sent to USDA	3/99	
5 Solicit Risk Management Options	5/19/99	
6 Develop Risk Management Strategy		

## Phase 1: "Error Only" Review by Registrant

- No substantive corrections to health effects assessment.
- No substantive corrections to ecological assessment.

#### **Phase 2: Open Public Docket**

• 60-day public comment period.

#### **Phase 3: Public Comment**

- Comments received from registrant, public interest groups, growers, USDA
- Importance to agriculture
- Used extensively in IPM programs
- Few alternatives for some crop/pests combinations
- Growers' comments noted:
  - importance for codling moth control on cherries;
  - lack of good alternatives on apples;
  - important quarantine use for almonds.
- Additional data received from registrants, growers

## New Data Received During Comment Period

• Information on use practices

## New Data Received After Comment Period Closed

- Dermal exposure studies
  - cotton
  - apples
- Revised Monte-Carlo with data files

## Phase 4: Revise Assessments, Solicit Comments from USDA

- Revisions to acute dietary assessment including:
  - Use of probabilistic model (Monte-Carlo)
  - Use of monitoring data (PDP & FDA)
  - Updated consumption data and percent crop treated
- Revisions to worker risk assessment include:
  - Use of Agricultural Task Force data to calculate REIs
- Preliminary comments from USDA on health effects assessment
- Comments and revisions to ecological assessment
  - In progress

#### **Already Made Substantial Revisions**

- Used available monitoring data for dietary assessment
- Developed in-house Monte-Carlo capabilities
- Ability to perform sensitivity analysis
- Incorporated worker exposure data from industry task force

#### Work-in-Progress

- Considering comments on environmental assessment
- Revising assessment based on revised labels and new data

## Regulatory History

Registration Standard

Louisiana Sugarcane Agreement

Acute Worker Risk Strategy

## Regulatory History (cont.)

#### **EPA/California Actions**

- Mitigation actions (worker)
  - California emergency regulations (6/98)
  - EPA incorporates much of California mitigation onto Federal labels (approved)
  - California issues emergency regulations virtually identical to Federal labeling requirements (4/99)

## Regulatory History (cont.)

#### **EPA/California Assessments**

- Similarities in assessments
  - Exposure assessment similar
  - Cholinesterase inhibition (RBC)
- Differences in assessments
  - California used human oral study with dermal absorption factor
  - EPA used animal dermal study

#### Use Profile

- First Registered for Food Use in 1959
- Currently Registered Uses
  - About 50 food uses
- Sources of Use Data
  - USDA/NASS
  - California
  - Other sources (e.g., growers and registrant)

### Use Profile (cont.)

#### Usage

- Two million pounds used per year (on average)
  - About 50% on fruit trees
     About 15% on nut crops
  - About 20% on cotton

#### **High-Use Food Crops**

- > 50% crop treated for apples, pears, and cherries
- > 20% crop treated blueberries, almonds, pistachios, and cranberries

#### **Major Use Regions**

- California and Pacific Northwest on tree crops
- Delta states and Texas on tree crops and cotton

### Use Profile (cont.)

#### **Use Practices**

- Application Methods
  - ground boom
  - airblast
  - aerial
- Use Rates
  - number of applications
  - pounds per acre
- Reentry Intervals

## Use Profile (cont.)

#### **Examples of Use Information Incorporated into Risk Assessments**

Crop	% Crop Treated		Application Rate (lb. ai)		Number of Applications		PHI	REI
	Max.	Wt. Avg.	Max.	Typical	Max.	Typical	(days)	(days)
Cotton	11	6	1.0	0.2	4	2.4	2	2
Tomatoes (fresh)	10	6	1.5	1.2	4	1.0	14	2
Apples	88	71	1.5	0.7	4	3.2	14	14
Peaches	30	21	2.0	0.7	NS	2.9	14	14
Pears	91	70	2.0	1.0	NS	2.5	14	14

## Human Health Risk Assessment



## Risk Assessment Components

- Dietary
  - Food
  - Drinking Water
- Aggregate
- Occupational

## Basic Risk Equation

Risk = Hazard x Exposure, where

 $Exposure = Consumption \ x \ Residue$ 

### Dietary Risk Assessments

#### Acute

Risk assessment
 reflecting one-day
 dietary exposures to
 pesticide residues

#### Chronic

Risk assessment
reflecting lifetime
(long-term)
exposures to
pesticide residues

#### Effect Levels

- Lowest Observed Adverse Effect Level = LOAEL
  - Is the lowest dose at which an "adverse" health effect is seen. Has units of mg per kg body weight per day.
- No Observed Adverse Effect Level = NOAEL
  - Is the dose at which no "adverse" health effect is seen.
     This dose is less than the LOAEL. Has units of mg per kg body weight per day.

## Acute Hazard (toxicity)

- From: Rat acute neurotoxicity study
- **Endpoint** (toxic effect):
  - plasma, RBC, and brain cholinesterase inhibition
- NOAEL: not determined
- LOAEL: 1.0 mg/kgBW/day

Endpoints from this study most accurately reflect toxicity which could result from one-day dietary exposure to azinphos-methyl.

## Chronic Hazard (toxicity)

- From: 1-year chronic toxicity study in dogs
- **Endpoint** (toxic effect):
  - RBC cholinesterase inhibition
- NOAEL: 0.15 mg/kgBW/day
- LOAEL: 0.70 mg/kgBW/day

Endpoints from this study most accurately reflect toxicity which could result from long-term dietary exposure to azinphos-methyl.

### Uncertainty Factors

• 10X Interspecies Variability

• 10X Intraspecies Sensitivity

• 3X Lack of a NOAEL (acute only)

Removed FQPA Safety Factor

• 300X Total for Acute

• 100X Total for Chronic

This would have been a typical type of uncertainty analysis, even before FQPA.

### Reference Doses for Azinphos-Methyl

LOAEL = acute RfD = 0.003 mg/kgBW/day UF

NOAEL = chronic RfD = 0.0015 mg/kgBW/day UF

$$%RfD = Exposure \times 100$$
 $RfD$ 

## Analysis of Special Sensitivity of Infants and Children

- No developmental effects in fetuses below maternally toxic doses.
- No increased sensitivity in pups relative to adults.
- No abnormalities in developing fetal nervous system.
- No neuropathology.
- Complete toxicity database.
- Good data -- unlikely that exposures are underestimated.

Determination made not to require developmental neurotoxicity study (however, issue of requiring DNT for a much broader category of pesticides is being considered by the Agency).

## Exposure -- Consumption

- USDA's Continuing Survey of Food Intake by Individuals (CSFII) 1989-91 Data
  - 1994-96 data are being validated for use in the near future
  - Supplemental children's consumption data
  - Due in December 1999

## Exposure -- Residues

Tier	Residue Data Used
1	Tolerance level residues
2	Field trial residues
3	Monitoring data:
	USDA PDP data
	FDA data
	Market basket data

As we move through the tiers, we refine our risk estimates because we use residue data closer to the point of consumption.

## Chronic Dietary Risk Assessments

- Chronic dietary risks were below levels of concern using high-end residues from field trials (Tier 2/3).
- Any further refinement of exposure estimates using monitoring data would lower risk estimates.
- Chronic risk estimate stopped and focus shifted to acute dietary risk assessment.

## Chronic Dietary Analysis Results

Risk Estimates as a Percentage of the cRfD (Tier 2/3)

Population	% cRfD
General U.S.	13%
Non-nursing infants < 1 yr	54%
Children 1-6	33%
Children 7-12	22%

Tier 2/3 used high-end residue data from field trials, some FDA monitoring data, and incorporated percent crop treated information. The chronic dietary risk assessment was done using DRES (the Dietary Risk Evaluation System).

## Types of Risk Assessments

- Acute Dietary: Conducted tier 1 (non-probabilistic) and tier 3 (probabilistic) assessments.
  - Tier 1 assumed tolerance level residues and 100% of crop treated.
  - Tier 3 used monitoring data and incorporated information on percent of crop treated.

#### Monitoring Data Used:

- USDA's Pesticide Data Program (PDP) Data
  - Statistically designed for dietary risk assessment
  - Important infants' and children's food sampled
  - Prepared as in the home (e.g., washing and peeling)
- FDA Surveillance Monitoring Data
  - Designed for tolerance enforcement
  - Large number of samples and types of food

## Two Types of Acute Dietary Risk Assessments

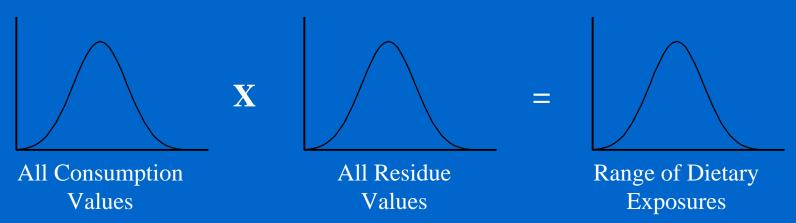
#### **Non-Probabilistic**



Assumes that every piece of fruit or vegetable consumed has residues at a high level. Therefore, a consumer's chance of consuming a high-residue piece of fruit or vegetable depends entirely on whether he or she eats that fruit or vegetable.

## Two Types of Acute Dietary Risk Assessments (cont.)

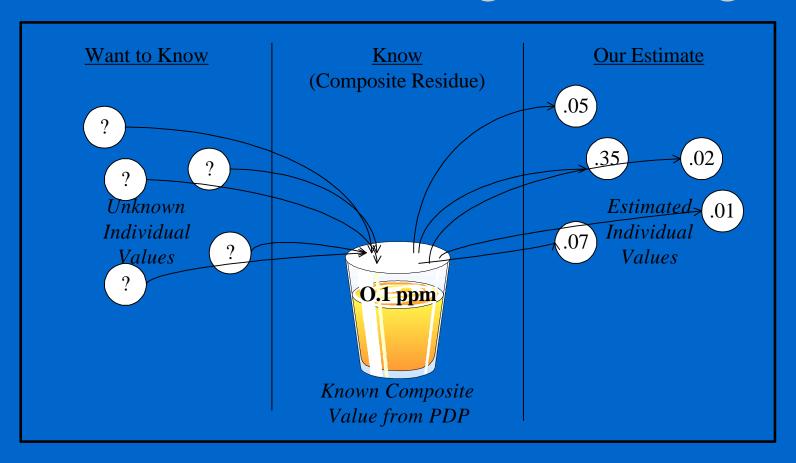
#### **Probabilistic**



Assumes that any one piece of fruit or vegetable consumed can have residues anywhere in the range of residues observed. Therefore, a consumer's chance of consuming a high-residue piece of fruit or vegetable depends both on how much of the item he or she eats AND how frequently that item is found to have high residues.

More realistic exposure estimates.

# Adjusting Composite Monitoring Data to Reflect Single Servings



# Residue Data Used for Acute Dietary

- USDA Pesticide Data Program (PDP) Data ~ 80% of foods

  FDA Surveillance Monitoring Data >80% consumption
- Field Trial Data: (19 food types, many low consumption foods, e.g., green cabbage, savoy cabbage)
- Processing Data: (e.g., cooking factor for apples)
- Baby food treated same as other processed foods

**NOTE**: Monitoring data were translated to similar crops if the crops had similar use patterns (e.g., orange juice to tangerine juice).

See Attachment I of Overview.

# Examples of Residue Data Used

Crop/Commodity Specific Residue Data Used in Acute Dietary Risk Assessment		
Crop/Commodity	Residue Data Used	
Apples (single servings)	Residue data from single servings of pears used as a distribution incorporating 88% of crop-treated. Source: USDA's PDP.	
Apples (cooked)	Residue data from composited (mixed) samples of apples plus a cooking factor used as a point estimate. Source: USDA's PDP.	
Apple juice (cider)	Residue data from apple juice used as a distribution. Source: USDA's PDP.	
Grape juice	Residue data from grapes incorporating 2% of crop-treated, and a processing factor used as a point estimate. Source: USDA's PDP.	

# Acute Dietary Analysis Results (Food Only)

#### Risk Estimates as a Percentage of the Acute RfD (%aRfD)

	Percentile			
Population	95th <sup>1</sup>	99.9th <sup>2</sup> March 1, 1999	99.9th² April 27, 1999	99.9th² May 19, 1999
General U.S.	4670%	85%	68%	59%
Infants < 1 yr	10,000%	331%	105%	100%
Children 1-6	10,000%	202%	135%	130%
Children 7-12	NR	129%	98%	90%

<sup>1</sup>Tier 1 non-probabilistic: Risk @ 95<sup>th</sup> percentile of exposure <sup>2</sup>Tier 3 probabilistic: Risk @ 99.9th percentile of exposure

# Acute Dietary Analysis Results (Food Only)

#### Risk Estimates as a Percentage of the Acute RfD (%aRfD)

Population	Percentile @ Tier 3 99.9th May 19, 1999	Percentile @ 100% aRfD
General U.S.	59%	NA
Infants < 1 yr	100%	NA
Children 1-6	130%	99.84th
Children 7-12	90%	NA

## Acute Dietary Results to Date

# Refinements made between successive assessments

- New percent crop-treated for many commodities
- Use of new single-serving pear data
- Revised assessment for canned fruit
- FDA monitoring data on cherries

# Acute Dietary Results to Date (cont.)

#### **Contributors to Risk Estimates:**

Major contributors: apples, pears, peaches

#### **Non-Detectable Residues:**

- Used zeros for portion of crop not treated and half the LOD for portion of crop treated which showed non-detects
- For crops with multiple years of all non-detects, conducted analysis using all zeros; no impact on risk assessment

# Acute Dietary Risk Assessment: Summary

- Methodology developed allowing use of PDP and FDA monitoring data for 80% of foods treated with azinphos-methyl, including major contributors to risk.
- Used most current information on percent of crop treated for all foods.
- Completed sensitivity analysis to determine that contribution of non-detectable residues to total risk for certain commodities was negligible.
- Completed analyses for various population subgroups including infants and children.
- Sensitivity analysis of tail of exposure values above 99.9<sup>th</sup> percentile to assess if the values are representative of real consumption/residue patterns -- in progress.

# Drinking Water Risk Assessment

- Assessment conducted because of azinphos-methyl's use pattern and environmental fate profile.
- Environmental fate data indicate azinphos-methyl can get into surface water and ground water to some extent.
- Available monitoring data are limited and there are some uncertainties associated with it.
- We expect some exposure in drinking water, therefore, we expect some contribution to risk.
- Concerns raised in the preliminary assessment warrant additional monitoring.

## Drinking Water Risk Assessment (cont.)

- Determined exposure to AZM in food first, then considered any remaining allowable exposure in drinking water.
- Example:
  - For children 1-6, 33% of chronic RfD used by exposure through food
  - 67% of the chronic RfD remaining for exposure through drinking water
- Drinking water exposure based on model estimates were less than 67% of chronic RfD.
- Conclude: chronic exposure to AZM in drinking water not a concern.
- Screening-level assessment considered health-protective because drinking water exposures based on model estimates are higher than actual exposures expected.

## Aggregate Risk Assessment

- Includes exposures from various sources:
  - food,
  - drinking water,
  - and residential and other non-occupational.
- No registered residential and non-occupational uses of azinphos-methyl.
  - For example, it is not used in homes, lawns, golf courses, etc.
- Aggregate risk assessment for azinphos-methyl would include food and drinking water only.

### Aggregate Risk Assessment (cont.)

- Acute aggregate risk assessment indicates no room for exposure in drinking water because the risk estimate for exposure through food alone exceeds EPA's level of concern.
- Chronic aggregate risk assessment: Not of concern
  - Combined food exposures and estimates of exposure from models for drinking water are not of concern.

# Occupational Risk Assessments Conducted for Azinphos-Methyl

#### **Handlers**

includes
professional
pesticide
applicators and
farmer/growers
who mix, load and
apply pesticides.

# **Post-Application Workers**

includes workers
who prune, thin,
hoe, prop, and
harvest crops
following pesticide
application.

# Factors Forming the Basis for Handler Risk Assessment

- Formulation and application equipment (e.g., wettable powder, airblast sprayer)
- Unit exposure (mg ai/lb ai handled)
- Rate of application (lb ai/acre)
- Areas treated per day (e.g., acres/day)
- Toxicity endpoint (mg/kg/day)
- Levels of protection

#### **Handler Risk Calculation**

Dose = (unit exposure) x (appl. rate) x (acres/day) x (dermal absorption%)Body Weight

$$MOE = NOAEL (mg/kg/day)$$
  
Dose (mg/kg/day)

•Correction for dermal absorption is required for intermediate term risk assessment

Handler Scenarios: (includes representative crops)

#### **Mixing/Loading Liquids for:**

- (1a) aerial application on cotton and tomatoes;
- (1b) groundboom application on potatoes and tomatoes;
- (1c) airblast sprayer application on pecans, citrus, grapes, apples, and plums/prunes/peaches

# Mixing/Loading Wettable Powders for:

- (2a) aerial application on alfalfa and tomatoes;
- (2b) groundboom application on potatoes and tomatoes;
- (2c) airblast sprayer application on almonds, citrus, grapes, apples, and plums/prunes/peaches

#### Handler Scenarios (cont.)

#### **Applying Liquid Spray by:**

- (3) fixed-wing aircraft on cotton and tomatoes
- (4) helicopter on cotton and tomatoes
- (5) groundboom on potatoes and tomatoes
- (6) airblast sprayer on almonds, citrus, grapes, apples and plums/prunes/peaches

Handler Scenarios (cont.)

#### Mixing/Loading/Applying by:

- (7) low pressure handwand on ornamentals
- (8) high pressure handwand on ornamentals

Results of Assessment for Airblast Application of Liquid Formulation (20 acres of crop per day at a rate of 1 lb AZM / acre)

Activity	Exposure of Concern	MOEs with Protective Clothing*	MOEs with Engineering Controls**
Mixing/Loading	Short-term dermal	80	224
	Intermediate-term dermal	51	140
Applying	Short-term dermal	16	112
	Intermediate-term dermal	10	72

<sup>\*</sup>Typical label protective clothing requirements for mixing/loading and applying liquid formulations:

Coveralls over long-sleeved shirt and long-legged pants, chemical-resistant gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant apron.

Closed mixing and loading system with gloves (as required by WPS), and enclosed cab tractors for applicators. These controls reduce the unit exposures by 98%.

<sup>\*\*</sup>Typical label engineering controls:

# Results for Short- and Intermediate-Term Handler Risks:

 None of the 12 handler scenarios (mixing/loading/applying combined) has an MOE above 100 when considering both short and intermediate exposure.

# Factors Forming the Basis for Post-Application Worker Risk

- Dislodgeable Foliar Residues (DFR):
  - amount of residue that workers could contact in field.
- Transfer Coefficient (Tc):
  - indicator of amount that workers actually contact during various field activities.

#### **Post-Application Worker Risk Calculation**

Dose =  $\frac{DFR (ug/cm2) \times Tc (cm2/hour) \times 8 \text{ hours}}{Body Weight (kg)}$ 

MOE = NOAEL (mg/kg/day)

Dose (mg/kg/day)

#### **Sources of Information**

#### **DFR Data:**

- Data used from studies on tomatoes, potatoes, apples, grapes, and cotton submitted by registrant.
- Most recent data on apples and cotton from studies submitted by registrant under a large Agricultural Data Call-In (DCI) issued by the Agency in 1995.

#### **Transfer Coefficients:**

- For orchard and citrus crops:
  - developed by California Department of Pesticide Regulation
     (CDPR) from azinphos-methyl exposure studies.

#### **Post-Application Risk Assessment Results**

- Risk estimates for reentry workers for all uses of azinphos-methyl (except its use in the WP50 formulation on tomatoes at 1.5 lbs ai/acre) pose serious risk concerns based on current application rates and REIs.
- Many REIs are currently two days (except for stone and pome fruits and nut crops at 14 days, grapes at 21days, and citrus at 30 days).
- Some Results for Other Crops Studied:

Crop	MOE	Day and Application Rate
Potatoes	47	Day 2 following 0.75 lb ai/acre
Apples	0.7	Day 14 following 1 lb ai/acre
Citrus	4	Day 30 following 2 lb ai/acre
Grapes	0.4	Day 21 following 0.25 lb ai/acre
Cotton	62	Day 2 following 0.25 lb ai/acre

# Azinphos-Methyl Cholinesterase Monitoring

- California (1985) 542 agricultural OP/carbamate applicators monitored for plasma cholinesterase inhibition
  - Cholinesterase depressed by 20% or greater in 127 workers
  - Azinphos involved in 10 of 94 cases where specific pesticides were able to be identified

# Azinphos-Methyl Cholinesterase Monitoring (cont.)

- Peach harvesters in California (1994) exhibit 19% decline in RBC cholinesterase in one study, and 10-20% in a second study
- Peach harvesters in California (1994) exhibit 12% decline in plasma cholinesterase

Findings such as these confirm the cholinesterase depression in post-application workers exposed to azinphos-methyl predicted in EPA assessment.

# Azinphos-Methyl Incidents

- California 1982-1990 134 cases involving AZM, 62 cases AZM was primarily responsible (10 cases reported 1990-94 suggests decline)
  - 25 cases in 1987 due to spray drift to residential area
- Poison Control Centers 1985-92 39 occupational,
   76 non-occupational symptomatic cases
  - Estimated hazard similar to other OPs based on a variety of measures
- Poison Control Centers 1993-96 14 occupational, 49 non-occupational symptomatic cases

# Ecological Assessment

### Public Comment Period on Preliminary Assessment Closed 3/99

#### **Comments Received:**

- Registrant:
  - Focused on fate and water issues
- Grower Groups:
  - Focused on typical application methods
- Washington State Department of Agriculture:
  - Focused on toxicity to bees

## **Ecological Concerns**

#### **Concern for Aquatic Organisms Based on:**

- Calculated estimates exceed acute and chronic levels of concern
- Extensive reported incidents
  - Many fish kill reports relative to other pesticides
  - Many fish killed in individual incidents
  - About 50% of incidents in OPP's data base are associated with azinphos-methyl use
  - Primarily associated with sugarcane and cotton uses
- Efforts made to address concern
  - Prescriptive use on sugarcane
  - Reduction in maximum number of applications for cotton

#### **Concern for Terrestrial Organisms Based on:**

Exceedence of both acute and chronic LOCs

# Summary and Conclusion

★ Acute Dietary Risks
★ Worker Risks
★ Ecological Risks
★ Additional Data
★ Phase 5

### Summary of Acute Dietary Risk Assessment

- Some risks of concern at 99.9 percentile
- Probabilistic assessment used predominately PDP and FDA monitoring data.
- New methodology used is being refined and will be peer reviewed.
- Assessment does not include potential additional contributions to risk estimates from drinking water.

### Summary of Worker Risk Assessment

#### **Handler Exposure (Mixer/Loader/Applicator)**

- Risk of concern for most scenarios.
- No chemical specific data available, so PHED data were used.
- Combined dermal & inhalation risks were calculated based on the maximum PPE and/or engineering controls.
- Risk mitigation proposed by registrants will help; however, risk estimates still remain of concern.

### Summary of Worker Risk Assessment (cont.)

#### **Post-Application Reentry Exposure**

- Risk of concern for most scenarios.
- Chemical-specific studies were used for estimating post-application worker exposure.
- New Dislodgeable Foliar Residue Studies were used in the assessment.
- Transfer coefficients used showed how readily residues transfer from foliage to workers who contact treated foliage.
- Risk to reentry workers is still above EPA's level of concern for several crops; therefore, further mitigation is needed. 66

# Summary of Preliminary Ecological Assessment

#### Aquatic

- Calculated risk estimates are high
- Fish kill incidents
- Some use restriction already in place

#### **Terrestrial**

Calculated risk estimates are high

### Additional Data

#### **Acute Dietary Exposure**

- Refinements of % crop treated data (complete)
- USDA PDP single serving pear data (complete)
- Applesauce residue monitoring study- The Apple Processors Association (2Q/00)
- New apple processing study-Bayer (2Q/99)
- Cherry processing study-Cherry Marketing Institute (2Q/99)
- USDA PDP single serving on apples-USDA(4Q/99)
- Single serving market basket survey focusing on "kids' foods"- Industry Task Force (2Q/00)
- Reduction of residues study in "packing houses"- Bayer (2Q/99)
- New field trials on apples using lower application rate-Bayer (3Q/99)
- Surface & ground water monitoring studies are needed for the Drinking Water Risk Assessment

## Additional Data (cont.)

#### **Acute Dietary Toxicological Endpoint**

Human oral study (submitted 3/22/99)

#### **Worker Exposure**

- Label changes (complete)
- Occupational monitoring study needed to verify reduced exposure with closed systems (suggested)

#### **Acute Worker Toxicological Endpoint**

• Human dermal study (submitted 3/5/99)

#### Phase 5

- Technical Briefing
- Revised risk assessment available in public docket and on the internet
- Begin 60-day public participation period
- Public submits risk management ideas
- Opportunities for growers and others to meet with EPA